

**Notice of Allowability**

Application No.

09/655,815

Examiner

Thai-An N Ton

Applicant(s)

LANZA ET AL.

Art Unit

1632

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/23/03.
2. ☒ The allowed claim(s) is/are 1-7 and 11-14.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)          |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. _____. |
| 3 <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No. _____  | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment                  |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance            |
|   | 9 <input type="checkbox"/> Other  |

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Joseph Bennett-Paris on February 3, 2004.

#### In the claims:

1. Replace claim 1 with the following:
  1. A method of testing the immune compatibility of cloned cells or tissues in a non-human mammal model, comprising:
    - a. obtaining a donor cell from a non-human donor mammal;
    - b. removing the nuclear DNA from a recipient oocyte, transferring the nucleus from said donor cell into the recipient oocyte to form a nuclear transfer unit, activating the nuclear transfer unit and culturing the nuclear transfer unit under conditions that result in the generation of a non-human embryo;
    - c. isolating an embryo having at least one cell, an embryonic disc or a stem cell from said non-human embryo;
    - d. injecting said embryo, embryonic disc, or stem cell into said non-human donor mammal at the same time as a control embryonic disc or stem cell; and

- e. examining the injection site for teratoma formation and signs of rejection of the injected cells, or of teratomas derived therefrom, to test the immune compatibility of the cloned cells or tissues.

2. Replace claim 3 with the following:

- 3. The method of claim 1, wherein said donor and control embryonic discs or stem cell are injected subcutaneously, or into the paralumbar fascia.

3. Replace claim 11 with the following:

- 11. A method to evaluate potential developmental signals that control cell differentiation comprising:
  - a. obtaining a donor cell from a non-human donor mammal;
  - b. removing the nuclear DNA from a recipient oocyte, transferring the nucleus from said donor cell into the recipient oocyte to form a nuclear transfer unit, activating the nuclear transfer unit and culturing the nuclear transfer unit under conditions that result in the generation of a non-human embryo;
  - c. isolating an embryo having at least one cell, an embryonic disc or a stem cell from said non-human embryo;
  - d. injecting said embryo, embryonic disc, or stem cell into said non-human donor mammal to form a teratoma;
  - e. removing the teratoma, and examining the teratoma for the presence of germ layers;
  - f. separating the germ layers cells and using the cells in assays to evaluate potential developmental signals that control cell differentiation.

4. Replace claim 12 with the following:

12. A method of engineering a tissue, comprising:
  - a. obtaining a donor cell from a non-human donor mammal;
  - b. removing the nuclear DNA from a recipient oocyte, transferring the nucleus from said donor cell into the recipient oocyte to form a nuclear transfer unit, activating the nuclear transfer unit and culturing the nuclear transfer unit under conditions that result in the generation of a non-human embryo;
  - c. isolating an embryo having at least one cell, an embryonic disc or a stem cell from said non-human embryo;
  - d. injecting said embryo, embryonic disc, or stem cell into said non-human donor mammal to form a teratoma;
  - e. removing the teratoma, and examining the teratoma for the presence of germ layers;
  - f. separating the germ layer cells, if present, and using said cells to engineer a tissue.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the Examiner be unavailable, inquiries should be directed to Amy Nelson, Acting SPE of Art Unit 1632, at (571) 272-0804. Any administrative or procedural questions should be directed to William Phillips, Patent Analyst, at (571) 272-0548. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice

Application/Control Number: 09/655,815

Page 5

Art Unit: 1632

published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

TNT

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